UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: October 24, 2018

Subject: Efficacy Review for EPA Reg. No. 75757-2; CDG Solution 3000;
DP Barcode: 448077
E-Sub #: 30298

From: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: 10/24/2018

To: Demson Fuller PM 32 / Wanda Henson
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: CDG Environmental, LLC
301 Broadway, Suite 420
Bethlehem, PA 18015

Formulation from the Label:

Active Ingredient	% by wt.
Chlorine dioxide..	0.30%
Other Ingredients	99.70%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate/dilutable liquid

Submission type: Label amendment

Currently registered efficacy claim(s): This product is designed to purify potable water including hospital and cruise ship water systems, potable water for human consumption, and water for livestock.

Requested action(s): Add label non-food contact surface sanitization claims.

Documents considered in this review:

- Letter from applicant to EPA dated June 22, 2018
- Data Matrix (EPA Form 8570-35) dated June 22, 2018
- 2 new efficacy studies (MRID No. 50593601 and 50593602)
- Certificates of Analysis and Letter of Authorization
- Proposed label (identified as A570 – June 22, 2018, Label version (2) October 23, 2018)
- Application for Pesticide Registration (EPA Form 8570-1)
- Citation of Data Form (EPA Form 8570-34)
- Transmittal document

II AGENCY STANDARDS

OCSPP 810.2300:
Sanitizers for Use on Hard Surfaces – Efficacy Data Recommendations (Sept. 4, 2012)

Sanitizers for nonfood contact surfaces (water soluble powders, liquids, and spray products). These products, when used as directed, should reduce the number of test microorganisms on a treated surface over those of an untreated control surface. The following testing recommendations apply to products bearing label claims for effectiveness as sanitizers for inanimate hard surfaces other than those which come in contact with food or beverages (e.g., floors, walls, furnishings).

1. **Test Procedures**.
    a. The Agency recommends the test procedure in this paragraph: The American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) may be used (Ref. 1). Three product samples, representing three different batches, one of which should be ≥60 days old, should be tested against each test bacterium on each representative test surface depending on the uses proposed on the label. For hard, porous surface label claims use unglazed ceramic tile for hard, nonporous surface label claims use stainless steel carrier or glass slide, using 5 test carriers and 3 control carriers. The test microorganisms are: *Staphylococcus aureus* (*S. aureus*) American Type Culture Collection (ATCC 6538) and *Klebsiella pneumoniae* (*K. pneumoniae*) (ATCC 4352). *Enterobacter aerogenes* (*E. aerogenes)* (ATCC 13048) may be substituted for *K. pneumoniae*. The ASTM method states “an average of at least 7.5 x 10^5 organisms must have survived the inoculated control squares for the test to be valid.”
    b. Evaluation of sanitizing success for nonfood contact surface sanitizers. The results should demonstrate a reduction of ≥99.9% (a 3-$\log_{10}$ reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

III PROPOSED DIRECTIONS FOR USE

The proposed label (identified as, “New Registration: April 3, 2018”) provides the following directions for use:

Per the submitted label, the product, CDG Solution 3000, is intended for the purification of water which has previously treated in accordance with Safe Drinking water Act (SDWA), such as that provided by municipal water treatment facilities. Intended applications include: Treatment of Potable Water and Cooling water in hospital/healthcare facilities, nursing homes, hotels, commercial office buildings, government buildings, residential buildings, and ships; treatment of industrial process water, food processing water and livestock drinking water. The product also claims to control of biological slime in human and animal potable water systems, process water systems, and cooling towers. Directions on the proposed label and dosing equipment manual provided the following information regarding preparation and use of the product as described:

Treatment of Potable water for Human Consumption: Add CDG solution 3000 to water at a dose up to 2.0 ppm (2.0 mg/L) chlorine dioxide (a dilution ratio of 1:1500). Under USEPA regulations, drinking water intended for human consumption may not contain more than 0.8 ppm (0.8 mg/L) residual chlorine dioxide or more than 1.0 ppm (1.o mg/liter) chlorite ion.

Treatment of Water for Animal Consumption: Add CDG Solution 3000 to the water at dose of 5.0 ppm (5.0 mg/L) chlorine dioxide (a dilution ratio of 1:600).

Treatment of Cooling Water Systems to Control Biological Slime: Add CDG Solution 3000 to the water at a dose of 50 ppm (50 mg/L) chlorine dioxide (a dilution of 1:60), and circulate or let stand overnight. Drain and rinse with clean water before re-use. To prevent slime growth after initial treatment, add CDG Solution 3000 to the water supply at a dose of 5.0 ppm (5.0 mg/liter) chlorine dioxide (a dilution ratio of 1:600).

IV STUDY SUMMARIES

1.	MRID	50593601	Study Completion Date:	02/12/18		
Test organism(s) ☐ 1 ☒ 2 ☐ 3 ☐ 4+		*Klebsiella pneumoniae* (ATCC 4352) *Staphylococcus aureus* (ATCC 6538)				
Test Method		Efficacy of Sanitizers for Inanimate Non-Food Contact Surfaces				
Application Method		Hard surface carrier test method				
Test Substance Preparation	Name/ID	CDG Solution 3000				
	Lots: ☐ 1 ☐ 2 ☒ 3	170712-1, 170711-2, 170712-3				
	Preparation Details	15 mL + 985 mL 300 ppm hard water				
Soil load		N/A				
Carrier type, # per lot		Glass slide carriers, inoculated with 20µL test culture				
Test conditions		Contact time	5 min	Temp	20°C	RH N/A
Testing Lab, Lab Study ID		Accuratus Lab Services, Project No. A24333				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		No Protocol Deviations were identified. Amendment: due to a typographical error, the protocol was amended to correct a product batch number. Testing was conducted at the LCL.				

2.	MRID	50593602	Study Completion Date:	01/29/18		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Klebsiella pneumoniae* (ATCC 4352)				
Test Method		Efficacy of Sanitizers for Inanimate Non-Food Contact Surfaces				
Application Method		Hard surface carrier test method				
Test Substance Preparation	Name/ID	CDG Solution 3000				
	Lots: ☐ 1 ☐ 2 ☒ 3	170712-1, 170711-2, 170712-3				
	Preparation Details	30 mL + 970 mL 300 ppm hard water				
Soil load		N/A				
Carrier type, # per lot		Glass slide carriers, inoculated with 20µL test culture				
Test conditions		Contact time	5 min	Temp	20°C	RH N/A
Testing Lab, Lab Study ID		Accuratus Lab Services, Project No. A24789				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		No Protocol Amendments or Deviations were identified. Testing was conducted at the LCL.				

V STUDY RESULTS

Sanitizer for Non-Food Contact Surface Efficacy Results

MRID	Organism	% Reduction		
		170712-1	170711-2	170712-3
5 minute contact time 45 ppm Active Ingredient				
50593601	*Klebsiella pneumoniae* (ATCC 4352)	<99.5	<99.8	<99.5
	Average Log_{10}[CFU/Carrier]	7.16		
	Staphylococcus aureus (ATCC 6538)	>99.9	>99.9	>99.9
	Average Log_{10}[CFU/Carrier]	6.34		

Sanitizer for Non-Food Contact Surface Efficacy Results

MRID	Organism	% Reduction		
		170712-1	170711-2	170712-3
5 minute contact time 90 ppm Active Ingredient				
50593602	*Klebsiella pneumoniae* (ATCC 4352)	>99.999	>99.999	>99.999
	Average Log_{10}[CFU/Carrier]	6.43		

VI STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50593601	Sanitizer Non-food contact	Hard non-porous	45 ppm ClO_2 (15 mL disinfectant + 985 mL diluent)	5 minutes	No	300 ppm AOAC synthetic hard water	*Staphylococcus aureus*	YES
							Klebsiella pneumoniae	NO
50593602	Sanitizer Non-food contact	Hard non-porous	90 ppm ClO_2 (30 mL disinfectant + 970 mL diluent)	5 minutes	No	300 ppm AOAC synthetic hard water	*Klebsiella pneumoniae*	YES

VII LABEL COMMENTS

Label Identification: Label Version identified as, "A570 – June 22, 2018, Label version (2) October 23, 2018"

1. The proposed label claims that the product, CDG Solution 3000, is an effective sanitizer against the following organisms when diluted to 110 ppm active (1:27 dilution), for a 5-minute contact period:

    - *Klebsiella pneumoniae* ATCC 4352
    - *Staphylococcus aureus* ATCC 6538

    These claims are **acceptable** as they are supported by the submitted data (MRIDs 50593601 and 50593602)..

2. Make the following changes to the proposed label:
    - On page 3, remove "process water systems" and "cooling water systems" from the section on Legionella. These use sites are not supported by the submitted data and inclusion in this section is misleading. In addition, please add the following to this section:
        - "The use of this product is one component of a Legionella risk reduction strategy that may be included as part of an overall strategy for managing Legionella risk in building water systems, which is recommended by the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 188-2015, a practice standard that establishes minimum legionellosis risk management requirements for building water systems. Under actual operating conditions, chemical treatment alone may not be an effective approach for Legionella control.
        - Move this whole section to the "Human Water Systems" section on page 10.
    - Page 3, italicize S. aureus and S. enterica in the sanitization directions.
    - On page 4, further clarify "heavy contamination" (e.g. visibly cloudy).
    - On page 6, remove the directive to "prevent airborne and surface contamination".
    - Page 9, remove the directions for "Disinfection of process water for vegetable rinses, tanks and lines" or provide a data citation to support the claim.
    - On page 10, clarify the section titled "Disinfection of Potable Water for Human Consumption" to include that the product is intended to for use on water which has been previously treated in accordance with the Safe Drinking Water Act (SDWA), such as that provided by municipal water treatment facilities as is pointed out on page 1 of the label.

Note to PM: Please check the claim "CDG Solution 3000 may be used in the treatment of fruits and vegetables, poultry and red meant" (page 3) and the corresponding directions for use (page 13) as well as the directions for disinfection of processed fruit and vegetables as these claims may require prior FDA approval.